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March 9, 2020

Greetings,

The CDC has issued Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19) on 3/8/20, and can be found here: https://emergency.cdc.gov/han/2020/han00429.asp?deliveryName=USCDC_511-DM22106. Clinicians should be informed of this update if they are seeking guidance.

The CDC has issued another update: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19), today, that allows for the OP and NP swabs to be placed in the same Viral Transport Media. The update is found at this link: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html. Sending them in separate tubes is still acceptable.

We've seen some samples submitted with the test requisition in the same bag space as the primary containers. This will delay testing as the sample must be accessioned in a biosafety cabinet with special handling of the paperwork. PLEASE use bags with separate pouches for paperwork, or include requisitions in a manner that excludes contact with the primary container. The number of submissions will require a process that allows for safe and efficient accessioning in order to provide timely resulting. Your laboratory cooperation is appreciated.

Please call me if questions arise.

Thanks,
Bryan

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Utah Public Health Laboratory

Interim Guidelines for Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV)

Until more information becomes available, precautions should be taken in collecting and handling specimens that may contain 2019-nCoV. Timely communication between clinical, laboratory, and UDOH/Local Health Department staff is essential to minimize the risk incurred in handling specimens from patients with possible 2019-nCoV infection. General and specific biosafety and submission guidelines for handling, processing, and shipping 2019-nCoV specimens are provided below.

General Guidelines for 2019-nCoV

For initial diagnostic testing for 2019-nCoV, CDC recommends collecting and testing **upper respiratory** (nasopharyngeal AND oropharyngeal swabs), and **lower respiratory** (sputum, if possible) for those patients with productive coughs. Induction of sputum is not indicated. Collection of three specimen types, lower respiratory, upper respiratory and serum is encouraged. Store specimens at 2-8°C and ship to Utah Public Health Laboratory (UPHL) on ice packs. Label each specimen container with at least two unique identifiers. Frozen specimens should be shipped on dry ice with appropriate shipping protocols. Questions regarding laboratory response, specimen submission, or testing guidance can be directed to the UPHL Biothreat response team at 801-560-6586 (24/7).

Respiratory Specimens

A. Lower respiratory tract

1. Broncho alveolar lavage (BAL), tracheal aspirate

   Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

2. Sputum

   Refrigerate specimen (sterile, leak-proof, screw-cap sputum collection cup or sterile dry container) at 2-8°C and ship to UPHL on ice pack.

B. Upper respiratory tract: Nasopharyngeal swab AND oropharyngeal swab (NP/OP swab)

Use only synthetic fiber swabs with plastic shafts in sterile tubes containing 2-3 ml of **viral transport media.** NP and OP specimens should be kept in separate vials. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

C. Nasopharyngeal wash/aspirate or nasal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

Serum

Collect 1 tube (5-10 mL) of whole blood in a serum separator tube. A **minimum of 1 mL of whole blood** is needed for testing.

Serum separator tubes should be stored upright for at least 30 minutes, and then centrifuged at 1000–1300 relative centrifugal force (RCF) for 10 minutes before removing the serum and placing it in a separate sterile tube for shipping. Refrigerate the serum specimen at 2-8°C and ship to UPHL on ice pack.

At this time, diagnostic testing for 2019-nCoV can be conducted only at CDC. Shipment of specimens MUST be coordinated through the UDOH/UPHL.

Testing for other respiratory pathogens by the provider should be done as part of the initial evaluation and should not delay specimen shipping to CDC. If a PUI tests positive for another respiratory pathogen, after clinical evaluation and consultation with public health authorities, they may no longer be considered a PUI.

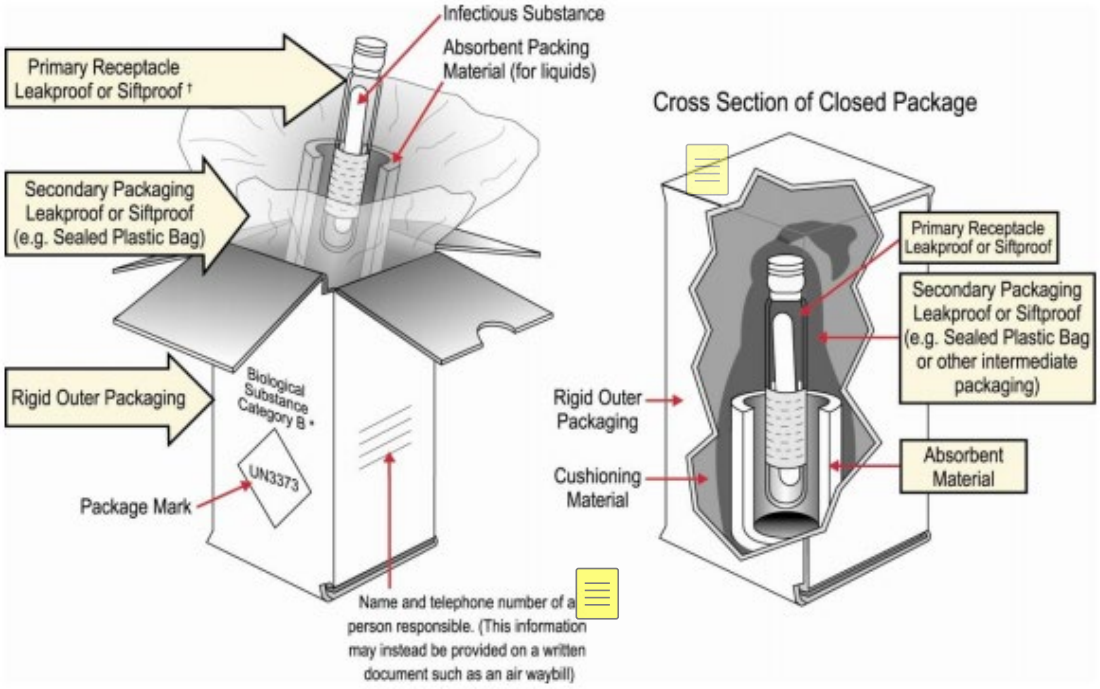
Note: Collection of stool and urine samples is encouraged. These samples should be stored frozen (-70 C) for further testing or studies.

Packing, Shipping and Transport

Packaging, shipping, and transport of specimens from suspect cases or PUI's of 2019-nCoV infection must follow the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations.

Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential 2019-nCoV specimens.

UN 3373 Category B schematic for packaging



General Biosafety Guidelines (for working with potentially infectious materials)

Clinical laboratories performing routine hematology, urinalysis, and clinical chemistry studies, and microbiology laboratories performing diagnostic tests on serum, blood, or urine specimens should follow standard laboratory practices, including Standard Precautions, when handling potential 2019-nCoV specimens. Appropriate physical containment devices (e.g., centrifuge safety buckets; sealed rotors) should be used for centrifugation. Ideally, rotors and buckets should be loaded and unloaded in a BSC.

Testing of PUI specimens that involve any procedure with the potential to generate fine-particulate aerosols or droplets (e.g., vortexing) should be performed in a Class II Biological Safety Cabinet (BSC). In the case of lack of access to a BSC, or any procedures outside of a BSC eye and face protection (e.g. goggles, mask, and face shield) or other physical barriers (e.g. splash shield) should be used to minimize the risk of exposure to laboratory staff.

After specimens are processed, decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against other respiratory pathogens, such as seasonal influenza and other human coronaviruses. Follow manufacturer's recommendations for use – dilution (i.e., concentration), contact time, and care in handling.

For 2019-nCoV laboratory waste, follow standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses.

Specific Biosafety Guidelines

The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Routine examination of bacterial and mycotic cultures
- Routine staining and microscopic analysis of **fixed** smears
- Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, **decontaminated primary container**.
- Inactivated specimens (e.g., specimens in nucleic acid extraction buffer)
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Electron microscopic studies with glutaraldehyde-fixed grids

The following activities involving manipulation of potentially infected specimens should be performed in a Class II BSC:

- **Aliquoting and/or diluting specimens**
- **Inoculating bacterial or mycological culture media**
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid **extraction procedures** involving potentially infected specimens
- **Preparation and chemical- or heat-fixing of smears for microscopic analysis**

For additional detailed instructions please refer to the following:

Biosafety in Microbiological and Biomedical Laboratories (BMBL) – Fifth Edition

Laboratory Biosafety Manual – Third Edition

https://www.cdc.gov/coronavirus/2019-nCoV/index.html